SIEMENS

MAMMOMAT Novation DR

SP

Update Instructions   SP015/04/P

Title: Removal of DROC and installation of WH AWS (syngo)

Reason for Update: ☒ Performance

Urgency:		☐ Immediate	☒ Within 4 months
Update material required?	☒ Yes	☐ No	
Materials free of charge?	☒ Yes	☐ No	
Return of parts?	☒ Yes	☐ No	
Estimated completion time:	8 hours	Number of CSE's: (1) one	
Customer application training?	☒ Yes	☐ No	

Systems/Products affected/System identifying IVK

Name	Material No.	Serial No.
MAMMOMAT Novation DR	66 46 900	1003, 1011 - 1016, 1018, 1021, 1022, 1025, 1026, 1028, 1029

Remark: n.a.

Components affected/to be modified

Name	Material No.	Serial No.	Component status affected
n.a.	n.a.	n.a.	n.a.

Remark: n.a.

Chg. Ref. No.:	127199 / 137572
Name:	St. Gyönyör
Dept.:	CS PS 24

       Doc. Gen. Date: 08.04

Document Revision Level

This document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order current revision levels.

Disclaimer

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Systems/Products Affected

Affected are MAMMOMAT Novation DR Full-Field Digital Mammography Systems delivered with the Direct Ray Operating Console DROC. The DROC is a SUN -Blade Acquisition Workstation equipped with a UNIX-based SOLARIS operating system. This DROC AWS was (and is still being) delivered to some customers on a temporary basis. All such DROC AWS will be eventually removed and they will be replaced by the *syngo*-based, "Women's Health Acquisition Workstation" WH AWS. The pace of this replacement, i.e. the speed of the update, will be determined by the availability of the WH AWS.

As the first leg of this update the serial numbers enumerated on the front page of this instruction will be updated. Depending upon the availability of WH AWS and upon the possibility of replacement further DROC AWS will be removed, WH AWS will be installed and put into operation. The Supply Chain Management - SCM - Department (Logistics) of the Business Unit SP will notify the responsible Project Managers of the Regional Units well in advance concerning when the new AWS can be delivered for which Customer.

Reason for the Update

The DROC Acquisition Workstation (a SUN-Blade computer with a Solaris Operating System, an EIZO TFT-LCD display device, a keyboard and a mouse), originally delivered with the MAMMOMAT Novation DR will be removed and the WH AWS with syngo software will be installed instead, as was agreed with the Customer when the original delivery of Mammomat Novation DR was contracted.

The DROC AWS was delivered to several customers in deviation from the specification due to difficulties supplying the specified WH AWS

Prerequisites

- As a result of this update, the computer with its storage devices (hard disk) will be disassembled and removed from the installation site. The customer must be informed about this fact. When informing the customer about the time and scope of this update a request to archive all images taken, i.e. to securely record and store them on a mass storage device within the network, or on off-line data carriers should also be conveyed to him.
This archiving should be performed by the customer's specialist for Information Technology equipment before the CSE proceeds to start the update. A formal confirmation from the customer stating that all patient-related data were securely archived and subsequently deleted from the DROC AWS may be requested.

NOTICE	**Only a DROC AWS with all images securely archived and all patient, or patient-related data deleted can be removed from the customer's premises and dispatched back to Headquarters.**

- The network configuration data entered and stored in the DROC (either according to the original checklist, or, possibly changed in the meantime) will be needed, as they will have to be fed into the corresponding masks of the WH AWS equipped with *syngo* software. These data will be transferred during the course of this update. The CSE should prepare for himself one copy of the original checklist containing these data.
This checklist should be kept at the system and actualized if and when changes in such data may occur. Information about these network configuration data can be found in Chapter 3 - Collecting configuration data of the document, title: Startup System- WH AWS, Print No: SPB7-250.815.02.01 / dt: 05.04. .

NOTICE	**Moreover, it is assumed that the CSE performing the update has knowledge of the current DROC AWS and was properly trained on WH AWS, and/or has satisfactory knowledge of *syngo* acquired in training and practice.**

- Unlike the DROC AWS, the *syngo*-based WH AWS makes it possible to connect the system to Siemens Remote Services. The preparation for this update should include investigating this possibility in cooperation with the Customer.
As mentioned in the Field Service Strategy, it is our declared aim to have as many Mammomat Novation DR systems connected to SRS as possible. The concept of such a connection is described on the Intranet homepage of Customer Services. Click the "Siemens Remote Services - Connectivity Toolkit" button. For more corresponding information see the technical documents titled:

"Siemens Remote Services - Planning Guide", Print No.: TDIT-000.891.01.03, and "Software - Installation of Siemens Remote Services (SRS)", Print No.: SP00-000.816.02.02.

These preparatory activities aren't included in the time range of this update, however, if carried out beforehand, the network configuration data for such a SRS connection may be entered in the *syngo*-based WH AWS during this update.

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Special Tools / Documents

Tools

- Set of Torxx screwdrivers (TX 20, - 25, - 30,)

- Mains (line) power cord extension with multiple sockets

- Two-three pieces of 3.5 inch empty, DOS formatted disks (data carriers) for saving files from DROC and then uploading them to the WH AWS, as well as for backup of WH AWS. A CD-ROM can equally be used as a data carrier, since the DROC can write data to a CD.

- RMI 156, ACR Mammo phantom (Siemens Med Material no.: 088 81 265)

- Compression plate simulator; (delivered with the Novation system)

- Collimator-mounted plexi; (delivered with the Novation system)

Documents (actually valid, some of them are included in the current delivery of the WH AWS):

- Doc. No: 10 050 540 AVD 01S 00; Unpacking and Repacking Instructions, this document is delivered in the package;

- Print No: SPB7-250.815.02.01 / dt: 05.04; MAMMOMAT Novation DR, Startup System - WH AWS:

- Print No: TDIT-000.891.01.03 / dt: 02.04; Siemens Remote Services - Planning Guide;

- Print No: SP00-000.816.02.02 / dt: 05.04; Software Installation of Siemens Remote Services (SRS);

- Print No: SPB7-250.815.01.01 / dt: 04.04; System Startup with WH AWS,

- Print No: SPB7-250.812.01.02 / dt: 06.04; Installation Instruction and Start-up (DROC);

- Print No. SPB7-250.816.02.01 / dt: 06.04; Software with syngo AWS,

- Order No: SPB7-250.623.02.01, Issue 05/04; MAMMOMAT Novation DR - Quality Control Manual (for systems with WH AWS),   Remark: use the US - version in the USA.

Ordering Information

No special material number will be defined for the kit. However, Sales numbers 04498080 (for WH AWS with color TFT monitor) or 04498031 (for WH AWS with grey scale, also called black-and-white TFT monitor) will be attached to the packaging box.
The kits will be assembled on a customer-specific basis here at the Logistics Dept. of the Business Unit SP. The SCM / Logistics Dept. of the BU SP will be in close contact with the responsible Project / Service Manager of each Regional unit concerned. That way the deliveries will be coordinated on a case-to-case basis.

Contents of the "Update kit"

The delivery will consist of:

- a computer with the Windows-based Operating System and the *syngo* software already loaded. The language and time zone settings will already be configured, they only will have to be cross-checked. (The delivery of the computer will also include the Windows operating system and the *syngo*-based acquisition software on separate data carriers (CD ROMs) and a data cable adaptor from DVI to VGA with two branches)

- a display device / a TFT-LCD monitor; either color, or black-and-white, according to the existing contract agreement with the customer,

- VGA-to-5 x BNC cable connecting the graphic interface to the monitor, via the above mentioned adapter,

- a country / language specific keyboard,

- power cords for the computer and for the display device,

- a mouse, (a Siemens/Fujitsu mouse and a three-button Logitech mouse may be delivered, the Logitech mouse - with three buttons - has to be installed).

- the appropriate dongle,

- a DIN A4 sheet with the licence,

- Instructions for Use, WH AWS QC-Manual ,

- technical documentation,

- this Update Instruction, and

- the Unpacking and Repacking Instructions, ID code: "10 050 540 AVD 01S 00".

The box / boxes in which the delivery arrives, will have to be used to send the removed parts back to the factory. Only the installing CSE is allowed to open them and unpack the merchandise, since he is also required to properly wrap the removed equipment for return delivery.

NOTICE	**The removed equipment is intended for further use. In order to avoid damage when removing, disassembling and packing such materials it is absolutely necessary to carry out these activities with appropriate care and according to the a.m. instruction.**
	Such care is requested from all personnel handling the materials during the entire return process. The standard CSML return process described in the ARTD must be used. The Return Parts Form must be duly filled in, declaring the materials as return from the UI SP015/04/P. Any delays in dispatching the merchandise for return shipment should be avoided. If damage occurs due to incorrect handling, recourse claims will be applied. It is expected that the return delivery will be dispatched back to CSML Warehouse in Dietzenbach /Germany immediately after the completion of the update. If the return delivery won't reach the Headquarter four (4) weeks after the dispatch of the exchange kit with the WH AWS, the price for the DROC AWS will be billed to the Regional Unit responsible.

Return of Parts

The following parts must be returned (see remark above concerning packing boxes). The extent of parts to be returned corresponds fully with the extent of new parts supplied.

- the removed DROC AWS, consisting of:.

    - the computer (SUN-Blade),
    - the display device / monitor (EIZO),
    - the keyboard and mouse,
    - the data and power cables,
    - licences and software data carriers (the Operating System and the Acquisition software) supplied with the original delivery of the DROC (on 4 + 2 CDs).

NOTE	**The service cable connecting the detector to the service PC and the CD-ROM with the detector data should not be returned.**

Return Address (for removed equipment)

> Logistics Service Center
> SIEMENS Medical Solutions
> c/o Geis Industrie-Service GmbH
> Waldstrasse 37
> 63128 DIETZENBACH,
> Germany

The lump-sum price of EURO 17.941,50 can be entered in the accompanying proforma invoice as the satatistical value for the entire return delivery.

Work Steps - Procedure

MAMMOMAT Novation DR SYSTEM SWITCH-ON

When switching the system ON, make sure that the Mammomat (and therefore the BRICK interface) is switched ON first. The AWS can be switched ON only after a delay of about 5 minutes. There is no special sequence for switching the entire system OFF.

DROC AWS ON

- After the arrival on site the CSE checks whether the MAMMOMAT Novation DR system is switched ON. If not, switch ON the system and run up the DROC application. The Startup procedure is according to Page 2 of Chapter 19 "Acquisition workstation" in the document titled: Installation Instructions and Start-up (DROC), Print No: SPB7-250.812.01.02 / dt: 06.04. During the run-up, the system host name should be noted down. Log in under the Account **apps**, appropriate password: apps. Log in under the Account **Andrea**, appropriate password: Andrea. Look under **Edit** and note down the currently available outputs.

PATIENT DATA

- Check whether there are any patient, or patient-related data stored on the hard disk. Entering asterisk * as patient name - wild card and clicking the Search button is not recommended. Such a search works only if few patients are recorded on the DROC AWS.
  It is recommended to seek confirmation about archiving and deletion of patient data from Customer.

- Check, whether there are any ERROR messages of "archiving failed" recorded. Click the ALARM button and evaluate the ERROR messages.

- Call in the Customer's representative, archive patient data, if any, and record the outcome if it is needed to perform such activities. Delete such patient data only after a successful archiving procedure.

BRICK TIMEOUT EXTENSION

- Perform the extension of BRICK timeout, (for this go to the Terminal window

    - either by clicking the Terminal icon on the desktop,
    - or by right-clicking on the desktop background,

      then select **Tools**,
        then select **Terminal** on the pop-up / drop-down menu.

- When in the Terminal window, type in: **telnet brick** and press Return - or Enter, depending upon the type of keyboard connected -).

- Log in under the user name (account): **root**, press Return / Enter, then use the appropriate password: brick - because you are actually initiating communication with the BRICK - and press Return / Enter.

⚠CAUTION	**It is very important to spell the command properly when typing it in. If an incorrect command is entered, the BRICK may suffer damage which will be very difficult to remedy. (Should reconnection of the DROC to the system be necessary for any reason, e.g. the installed WH AWS wouldn't work properly, the new value "1000" can stay in the BRICK.)**

- Type in: **xrayconfig host_timeouts save 1000** and press Return (or Enter).

- Type in: **reboot** and press Return / Enter. Wait approx. 5 minutes until rebooting has been completed.

- Press **Ctrl** and **C** simultaneously to close (interrupt) connection to the BRICK.

SAVING DETECTOR-SPECIFIC CONFIGURATION FILES FROM DROC

The detector-specific configuration files will first have to be transferred from the hard disk of the DROC to a floppy in order to upload them to the corresponding directory of the WH AWS later on. These are mainly the files: **.map**, **.cfg** and **.smj**. If a **qualify.log** file exists in the same directory, it should also be saved. Since the detector gain will have to be recalibrated, it isn't necessary to transfer the **.cal** file.

- Open the Solaris File Manager witha right-click on the desktop background, proceed by selecting the File Manager menu entry button under Files in Workspace,

     double-click **opt**

         double-click **linx_mp**

             double-click **opt**

                 double-click **DRUL_0.6.3**

                     double-click **data**

  where xyzu is the serial number of the detector array.

- Insert floppy into drive A:, open a second File Manager, select the appropriate device, Drive A: - by clicking **File** / **open floppy**. The floppy should have been formatted. If not, it can be formatted here. If the formatting procedure causes difficulties remove and reinsert the floppy, retry formatting, or retry formatting with another floppy.

- Highlight the mentioned files: **MPxyzu.map, MPxyzu.cfg, MPxyzu.smj**, and possibly **qualify.log** in the **data** directory, then go up to Selected in the drop-down menu and select copying to floppy. (The files can also be transferred by the mouse, i.e. via a drag-and-drop procedure.)

- Click on File eject, when the pop-up message allowing removal of the disk is displayed remove the floppy. Attach an adhesive label listing the files to the floppy. This floppy can be stored at the Customer's site.

MOVING, UNPACKING AND ASSEMBLING THE STAND-ALONE WH AWS

- Move the supplied packages into or near the examination room.

- Carefully open the packages as per Unpacking instructions and remove their contents.

- Assemble the WH AWS in a stand-alone configuration so that it will be near the DROC AWS, which is still in operation.

- Plug in the USB dongle in the middle USB connector (use the row of the USB connectors just above the sound card outlets, not the one below the power cords) on the rear wall of the computer. (The dongle has to be plugged into the same place it was in during the loading of the software. Otherwise the system won't be able to find the Licence file.)

- Plug in the Logitech mouse and the keyboard. These have special connectors with color coding.

- Plug the power cables into the computer and the monitor. The power supply of the monitor goes through the computer. To get to the power and data terminals of the monitor remove small cover at the back first using a Torxx driver if necessary.

- Connect the monitor to the graphic board. The graphic board is a special one (Matrox power desk), a branched adapter "DVI-to- 2 x VGA" from its DVI output socket should be supplied with the computer. This adapter has two VGA leads. Be sure to connect the video data cable to the connector marked **VGA 1**. The other branch with the VGA 2 connector remains dangling. It could drive another monitor, but that isn't foreseen here.

- The 5 lead BNC connector terminals on the monitor might be color-coded. The correct connection from top to bottom: red, green, blue, white / weiss and black / schwarz. At the other end of this data cable (material number 3065844) there is a VGA connector to be connected to the VGA1 connector of the adapter. If the monitor remains without signal, check the cable and the DVI-to-VGA adapter. In some cases the monitor may switch to a power saving mode indicating ing "without signal". This would disappear if any key on the keyboard is pressed.

- Connect the WH AWS to mains (line voltage) in this stand-alone configuration. Although the computer adapts to a wide range of voltages and frequencies, a cross-check is still recommended.

SWITCHING THE WH AWS ON.

- Switch the system ON.
  Remark: To switch the computer OFF, keep corresponding pushbutton pressed for some time.)

The technical document titled: Software with syngo AWS, Print No: SPB7-250.816.02.01 / dt: 06.04 is useful as reference. The entire software was loaded to the hard disk at the factory. The computer should start without difficulties.
Chapter 3 of the above mentioned document deals with reinstallation of the software if that should become necessary. It is recommended to read the document, especially Chapter 3. Remember that the WH AWS is still in a stand-alone mode, it is not yet connected to the Mammomat Novation system. The count would go on in a manner characteristic for *syngo*. If error messages, like: "The initialization of Mammomat failed", or something similar pop-up later on, ignore them and acknowledge with Cancel.

Here are some additional remarks on the description of reinstallation of the entire software on the WH AWS in the corresponding manual (which hopefully won't be necessary):

- Follow work steps as per Chapter 3 starting on the first page. The BIOS password is usually: pwd4sp.

- When you've removed the BIOS CD and inserted the WH AWS Installation CD as requested in work step 5, reset the system with **ctrl + alt + del**.

- If there is no "latest backup" - as requested in work step 18 - use the licence CD, since the system has recognized that no application licences are installed.

- Perform the procedure described in the paragraph "Installing network components" in the following way:
    - the connection to BRICK through the Light wave guides has to be established,
    - it is of no importance, whether or not the WH AWS is connected to the net,
    - Select **Options -> End Session -> logoff meduser,**
    - Log in under Windows, username **Administrator**. The appropriate password is: admpwd4$med
    - Run **Modem1.exe**, **Modem2.exe** and **Network.exe** , (press Carriage Return).

- At present the above mentioned document does not stress that if the software is reinstalled on site, the AEC Calibration tool can not be used immediately, because initially it is only stored as an automatically unzipping EXE-type file under AWS\Service\aeccaltool\zipped.exe on the partition C:\ of the hard disk . It only can be used if first unzipped into the directory C:\winnt\system32.

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LOADING DETECTOR-SPECIFIC FILES

The detector-specific configuration files from the floppy (where to they have been saved from the hard disk of DROC AWS a short while ago) will have to be loaded / copied to the hard disk of the WH AWS. The three (or four) files - **MPxyzu.map, MPxyzu.cfg, MPxyzu.smj**, and possibly the **qualify.log** - have to be copied to the following directory: **C:\aws\drul\data**.

- Insert floppy in drive A: of the WH AWS.

- Start the Explorer. You will have to copy the files to the directory C:\aws\drul\data. To do so first open the *syngo* service software by selecting **Options > Service > Local Service** in the window menu header.

- Check whether there are characters entered in the first (left) window of the service key and whether they correspond with those supplied on a DIN A4 sheet. Type them in, if necessary.
  Remark: The password and the licence key are supplied with the WH AWS on a DIN A4 sheet, usually wrapped in a transparent plastic sheath. Insert that sheath in the binder with the technical documentation for safekeeping.

- Enter the service / licence key (the last 6 characters into the 2nd field).

- Select **Set as default** in the small box.

NOTICE	**The service key is divided into two parts. For easier handling, the CSE works only with the last 6 characters. Since the current step causes the software to remember the first part as a default value, there is no need for the CSE to repeatedly type it in later.**

- Confirm the screen with **OK**. The **Service Software Home Menu** will then appear.

- Select **Utilities -> Escape to OS**. Enter the following command:
  start explorer
  A Windows XP Explorer window opens.

- Check whether there are any such detector-specific files in the directory **data**.

- If there are, they can/should be deleted, (these are the detector-specific data belonging to the detector integrated in the Novation system the WH AWS has been tested on at the factory).

- Copy the current files from the floppy to the **data** directory via drag-and-drop.

- Restart the syngo application. To do this go to **Utilities** in the service software and select the Source -> **System.**

  Utilities -> Escape to OS -> System
  Select **Restart Application** and press **Go** to restart the *syngo* application.

MANUAL TRANSFER OF NETWORK DATA FROM DROC TO WH AWS

- Prepare the original checklist with network configuration data - if available - near the DROC AWS.

- Prepare copies of pages 18 to 29 of the document Print No.: SPB7-250.815.02.01, titled: "MAMMOMAT Novation DR Startup System WH AWS" near the DROC AWS. These pages could help to collect data from the DROC in a systematical manner, as they will have to be entered in the WH AWS.

First step: Collecting or confirming configuration data from DROC

- Proceed according to the description in Chapter 19 of the document SPB7-250.812.01.02, titled MAMMOMAT Novation DR Installation Instructions and Start-up (DROC), as well as according to the hints given below:

Site network settings:

- readout the **Site network settings**, i.e.
    - the Site name,
    - phone number,
    - address and
    - contact

from the DROC, using the NETSCAPE browser. To do this:

- Log in with user name **apps** and the appropriate password: apps. This will allow to start and enter the Netscape browser.

- When within Netscape continue to log in with the user name **service** and the appropriate password: fixit.

- In Service Tools, select **Configuration -> DROC -> Site configuration**.

- Read the site information from the mask which then appears and record / write down data into page 18.

- When finished, return with the **Back** button of the browser.

Network configuration:

- In Service Tools, select **Configuration -> DROC -> Network Configuration**.

- Read registered data about the **network configuration** from the mask and record / write down these data on page19 for:
    - the DROC AWS (local host) name (also called: computer name),
    - the IP address, (also called interface IP address)
    - the Subnet screen (Interface netmask)
    - the IP Gateway(s) address (the Default Router).

The other data on page 19 are Windows related, i.e. are not usually used here. In order to go back, apply the **Back** button of the browser (here twice).

AE title of the MAMMOMAT Novation DR system:

It is also necessary to find the **AE title (the calling AE Title, device name) of the MAMMOMAT Novation DR system** as it was recorded in the DROC. The way to perform the original setting is described on page 19 - 8 of the document Print No.: SPB7-250.812.01.02. Usually the factory default setting **DIRECT_DIGXRAY** is left unchanged in the DROC. A change would be necessary - for example - if two or more Novation systems are connected to the network. (The actual AE Title of the Novation system can also be found - for instance - under **DROC -> Worklist configuration**.)

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Hardcopy camera / DICOM printer:

- In Service Tools, select the service shortcut **Configure output devices**.

- Click on **Browse -> installed cameras** (installed is/are that/those device/devices where the "Uninstall" entry is also present).

- Read registered data about the **Hardcopy camera / DICOM** printer from mask and record / write down those data on page 20.
    - hardcopy (camera) type:
    - device, host, or node name), the DICOM AE Title:
    - IP address (device address):
    - port (the numerical code following the colon):

- Repeat procedure if more devices are connected.

Archives:

- In Service Tools, select **Configure output devices**

- Click on B**rowse, physicians display / archives**

    edit -> edit config file

- Read registered data about the **Archive** from the mask and record / write down those data on page 21.

Viewing Stations, (MammoReport Plus, Magic view)

- In Service Tools / **Configure output devices**,

- Click on **Browse, physicians display**

    edit -> edit config file

- Read registered data about **Viewing Stations**, MammoReport Plus from the mask (takee the second or third entry "System config file" from the top, **not the top one!**) and record / write down those data on page 23.
    - IP Address (device address)
    - DICOM AET and port number (Device name)
        - Storage SCP -> AET:
        - port (the numerical code following the colon)
        - Q/R SCP (the Service Class Provider "MammoReport Plus" cannot query/retrieve, as yet.)

HIS / RIS Connection (Modality Worklist - MWL - Service)

Collect data on AET for HIS/RIS, see page 19 - 29 and following pages of the document SPB7-250.812.01.02.

Acquisition system:

These data are relevant only if imaging system(s) of other modalities is/are connected. This isn't relevant when collecting data from DROC, as the DROC doesn't allow for such connection. It is only the *syngo*-based WH AWS where such a connection is a possible feature.

RDIAG Server (LAN via Router):

This isn't relevant when collecting data from DROC, as the DROC doesn't allow for such connection. It is only the *syngo*-based WH AWS where such a connection is a possible feature. Usually there is a CSE in the Regional Unit specialized in connection of Imaging systems to Siemens Remote Services. If a Customer consents to such a connection, the assistance of that specialized CSE should be requested to prepare the network connection via router and enter the corresponding settings in the WH AWS.

WH AWS - MOVING INTO PLACE, CONNECTING LIGHT WAVE GUIDES AND THE NETWORK

The connection of whichever AWS to the BRICK (interface to the Novation system) is accomplished by means of two light wave guides. The connection works properly if the red LED on the side of the BRICK does not light up. Three LEDs are visible through the ventilation grid on the upper right side of the stand. The connector terminals of these two light wave guides are color-coded. The red colored one should be connected to the TX (transmit) receptacle, the black colored one should be connected to the RX (receive) receptacle .

NOTICE	**It is not necessary to switch the corresponding devices OFF when inserting or removing terminals of light wave guides to / from their corresponding receptacles (either on the AWS or on the BRICK).**

When connecting the WH AWS to the MAMMOMAT Novation DR system:

- Remove the two pegs plugged into the corresponding receptacles on the WH AWS.

- Remove the two light wave guides from their receptacles on the rear wall of the DROC AWS.

- Plug the two light wave guides into their corresponding receptacles at the rear of the WH AWS, observe the color coding.

- Check whether the red LED on the BRICK lights up. A red lit LED would signal communication problems between the AWS and the BRICK. This may be caused e.g. by unsatisfactory connection.

- Remove the network connection cable from the DROC.

- Insert the network connection cable plug in the corresponding socket on the WH AWS (near to the dongle).

Second step: Transferring, i.e. Entering configuration data in the WH AWS

As a result of the last work step the, WH AWS is still in the syngo application.

- The CSE will have to proceed according to pages 31 to 33 of the document Print No.: SPB7-250.815.02.01, titled: "MAMMOMAT Novation DR Startup System WH AWS", as well as according to hints below.

For special cases, like:
- Internet access via Proxy or Firewall,
- for HIS/RIS connection, etc,

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also read and proceed according to further pages of the above mentioned document.

- Start the *syngo* service software. (No user name or password needed.) To do so:

- Select **Options -> Service -> Local Service** in the window menu header. The service / licence key (6 characters in the 2nd field) of the password i.e. of the licence key supplied has to be entered (only the first part is fixed with the "Set as default" mark !), then select **Set as default**. (See LOAD DETECTOR-SPECIFIC FILES.)

- Confirm the screen with **OK**. The **Service Software Home Menu** will then appear.

- Select **Configuration**.

NOTICE	**The Configuration screens which then appear will contain only the initial (default) settings loaded at the factory, the DICOM Offline Device being the CD-ROM burner. The sequence of configuration steps should follow the structure displayed on the left side of the screen.**

Follow through

   Local host
      - Site Info
      - TCP /IP LAN
      - etc.

   Database

   Service

   DICOM

      - General
      - Character set
      - Off-line device
      - Network nodes
      - Print devices
      - etc.

   Import / Export
      - etc.

Carefully read and follow the NOTICES on pages 33 and 34 and, particularly - for the connection of HIS/RIS - on page 35. The required additional information can and should be obtained from the *syngo* on-line help function.

- when configuring cameras, always change grey scale to **12 bits**.

- when all data have been entered, leave the mask by clicking on **Home**. Rebooting is necessary to make changes, i.e. the data you have entered, effective.

QUESTIONS CONCERNING SIEMENS REMOTE SERVICES, NETWORK CONNECTION

In addition to the information in the pertaining documents all such questions can be directed to the Department of Customer Services, Group: SD24, Serviceability and Documentation - Special Systems at our Headquarters in Erlangen / Germany; (one possible telephone extension: +49 9131 84-7234)

DROC AWS - SHUT DOWN, SWITCH OFF, DISASSEMBLY, PACKING AND MOVING THE DROC

- Shut down the DROC in a regular manner. Since the DROC is already in a stand-alone mode, this action is of no significance. Switch the unit OFF, unplug all remaining cabling.

- Using the supplied Packing and Repacking Instructions carefully place the materials to be returned into the boxes, positioning the foam padding and small materials securely.

- Place and attach the Restriction advice ("Not for production", it is the last page of these instructions) on the top of the contents within the box.

- Place and attach the Return address specified in the Instructions at the top of the box. The print page from the end of these instructions can be used for this purpose.

- Prepare the box for safe dispatch, notify the responsible officials / administrators at the Customer's site that the box will be picked up by a forwarder after a corresponding call has been placed by the Logistics Department of Siemens' regional organization.

DETECTOR GAIN CALIBRATION

- Perform the Detector Gain Calibration according to Chapter 9 of the document SPB7-250.815.01.01. Follow the entire procedure as described on pages 8 to 13. The procedure requires 8 exposures, however, 12 images are preprogrammed (see bottom right corner of the monitor). You may delete four preprogrammed exposures (right-click of the mouse on the **Image** button) or end the procedure by **Forced closure** of the examination.

- as described under point 12, when the exposure is released on the Mammomat console you can see some short written messages on the status bar on the bottom of the monitor indicating the status. These messages will appear in the preset language. Their English equivalents are specified under point 12. Wait until the activity "Loading Image" has been completed and then decide whether to accept or reject it. Wait another 10 seconds for image reconstruction (calculation).

- Consider especially the point 13 on page 9 - 12 of the above mentioned document. The call for subjective evaluation of the image (of the recommended eight consecutive exposures, one after another) before accepting or rejecting them, actually requests searching for objects or artifacts in the images. See also the NOTE on page 9 - 13. The sometimes apparent difference in the grey scale of squares on the raw-data image is caused by the different sensitivity of the detector sectors and will be compensated for by image processing. (Image position coding: A - distal; R - Right)

- If pixel dropout or dead line(s) appear(s) in the images acquired during the detector gain calibration a new pixel map has to be generated. Proceed according to pages 9 - 14 to 19 of the same document.

- Repeat the detector gain calibration with the new pixel map .

Siemens AG
Medical Solutions

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CS PS 24

- As a test it is recommended to send an exposed image to the viewing station (e.g. MammoReport Plus). Check whether the image arrives and it can be viewed there.

QC-MANUAL, TEST NO: 1 & 6

- Perform

Test No: 1, "Acquisition Workstation Monitor check and viewing conditions" and
Test No: 6, "Phantom image Quality"
according to the Quality Control Manual, Print No. SPB7-250.623.02.01/ AG 05/04.

Proceed as described there. The SMPTE control image can be found stored in the WH AWS. The adjustment buttons of the new monitor may be locked. To actuate the lock/ unlock function, press the SET button once (1 x) and then the UP button three times (3 x).

ISSUES OF CONSTANCY TEST ON THE DISPLAY DEVICE / MONITOR

- Although the factory does not foresee any further activities in connection with Test No.:1, some additional issues may need to be considered. In some countries there are regulations regarding the luminance constancy over time of the display devices used, and regarding the values for windowing and centering in image postprocessing. If the previously installed EIZO monitor has been evaluated in this regard and if value(s) has / have been recorded (e.g. in Germany in connection with the §16 of the Rötgen-Verordnung = X-Ray regulation) questions may arise concerning

  - the adaptation and/or adjustment of the luminance of the newly installed monitor, or
  - the measurement of the new values and due alteration of the corresponding entries for luminance and windowing / centering in the report.

Experience shows that the second possibility can be followed. The reasoning that the AWS display device has not been released and is not intended for diagnostic evaluation of images, and therefore does not fall under the provision of such regulations, may not necessarily be accepted by all officials.

CHECK AND/OR REPROGRAMMING OF THE VALUES FOR OPDOSE

There are factory preprogrammed default values for the OPDOSE in the system. In this step, the current values of the system will have to be checked and, possibly reprogrammed. There are two places where change of the values has to be initiated. First the four possible thickness ranges of the (compressed) breasts have to be set, or changed - if the ranges currently set do not seem to fit. The description of how to program these ranges on systems with WH AWS can be found on page 4 - 14 in the document Print No.: SPB7-250.816.02.01.

- To perform this step, connect the service PC to the MAMMOMAT Novation stand and proceed according to page 4 - 3 and 4 of that document.

- When the Service program has started, select **Main menu -> Configuration -> Miscellaneous -> Auto limits.**

- Check whether upper thickness limits of the program keys are as follows:

  Program 1 => 29 mm;   Program 2 => 45 mm;   Program 3 => 59 mm;

- If different, change entries in these keys (i.e. type in upper limits) as given above.

If these given values of thickness ranges are correctly set and stored, then the programming of OPDOSE kV values for particular anode and filter material combinations can be done on the Novation operating console according to the Chapter Description of unit operation, Paragraph: Program Mode, in the Operator's manual Instructions for Use. Record set values and inform the Operator about the settings.

The following values are recommended (see table below):

Program	Compressed Thickness	Anode/Filter Combination	KV value	Dose level
1	0 - 20 mm	W / Rh	25 kV	H
2	30 - 45 mm	W / Rh	27 kV	H
3	46 - 59 mm	W / Rh	28 kV	H
4	60 and greater	W / Rh	32 kV	H

TESTING AND DEMONSTRATION TO CUSTOMER

As a test, it is recommended to send an exposed image of the RMI 156 Mammo phantom to the viewing station (e.g. MammoReport Plus) as well as to the configured printer(s). Check whether the image(s) has/have arrived, can be viewed, and are of acceptable quality.

If archive(s) is/are configured within the network, a test image should be sent to and retrieved from each archive. In case of an existing HIS/RIS connection, the Modality Worklist (MWL) Service, i.e. the data sent from the HIS/RIS, and the Modality Performed Procedure Steps, i.e. the data HIS/RIS is expecting from the Mammo X-Ray modality, should be tested. The presence of the hospital IT-specialist may be required.

- Co-ordination with the application specialist responsible for the training of the Customer's personnel immediately after a successful update is strongly recommended.

WH AWS BACKUP DATA

A backup of system-specific data, such as customer configuration entries, security settings, network nodes and EAETs is always necessary after software updates or system adjustments. Proceed according to pages 82 and 83 of the document
Print No.: SPB7-250.815.02.01.

EXCHANGE OF INSTRUCTIONS AND TECHNICAL DOCUMENTATION

The new delivery contains one light brown binder of user's documentation. This binder contains the Operator's Manual = Instructions for Use, the applicable QC-Manual and a List of Restrictions. The blue binder with technical documentation contains the pertaining Instructions and documents for service on the MAMMOMAT Novation DR with the WH AWS for the CSE. In the course of this update the CSE also has to cross-check the documents already on site, as they have been originally delivered with the system. The docu-

ments pertaining to those parts of the system not affected by this update will remain on site (e.g. Mammomat stand, generator, etc…)The documents pertaining to the DROC AWS have to be removed and, disposed of. If, in the case of some documents, their newer issues (with the revision level incremented) were included in the new delivery, the contents of the binders have to be updated. The data carriers (CD-ROM disks with the windows OS and *syngo* acquisition software) must be stored so that the CSE's future access is ensured. CSE should hand over both the binder containing the user's documents and the one with the technical documents. The user documents will be required immediately since application training should follow this update.

REPORTING (LINA - UPDATE HANDLING)

- Register 9 of the Technical documentation contains the the Product Status /(Revision level) list (Erzeugnisstandliste). The CSE should modify this as follows:
  in the row 24 enter text: n.a.
  in the row 28 enter text: 8380490 WH AWS 00;
  in the row 29 enter text: 8881109 SW WH AWS VA10B;

- The *syngo*-based WH AWS has material number 83 80 490, the current software version is VA10B. The performing CSE must enter his name and the date and signs the changes on the Product Status List.

- The delivered new materials include two serialized IVKs, the computer, material number 083 80 490, and the monitor, with the material number 080 30 991, if color, and material number 071 29 906, if grey scale. The report to P42 / LINA should reflect this fact.

- The returned materials also contain two serialized IVKs. The Siemens personnel responsible for maintaining/updating data in the P42/LINA should formulate the correct entry to reflect the fact, that these two IVKs (DROC and EIZO) left their functional location on their way to the factory in Germany.

- Following performance of UI SP015/04/P the report should be entered in the On-line reporting tool in the usual manner. A corresponding remark and the relevant data should be entered in the System logbook and signed by the CSE.

Gesperrt

für Neulieferung

Retoure aus der Umrüstung UI SP015/04/P !
Not for production – this is a return delivery
from an update!

SieMed Erl, CSPS24 - Aug. 2004

Inhalt:
Retoure aus der Umrüstung UI SP015/ 04/ P !
Content:
Returns from the Update Instruction 015/04 !

To:

Logistics Service Center
SIEMENS AG Medical Solutions

c/o Geis Industrie-Service, GmbH

Waldstrasse 37
63128   <u>DIETZENBACH</u>,
Germany

Aug. 2004 / MED Erl. CSPS24;

Completion Protocol

The update with the number **SP015/04/P** has been completed.

Material num-
ber: ....

Serial number: ....

Customer: .... Functional Loca-
tion: ....

Customer No.: ....

Name (CSE): .... Telephone: ....

Country: .... Location: ....

Date: .... Signature: ....

Remark: ....

....

| NOTE | **After completing the update, make a copy of this page, fill it out and file it in the corresponding System Binder/User Handbook.** |

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